Synsiro® Pro DES

The Next Level of Deliverability.
Proven Clinical Performance.[Δ]

- The next level of deliverability[1]
- Ultrathin struts[2]
- Outstanding patient outcomes[3]

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Synsiro® Pro DES

Vascular Intervention Coronary

The Synsiro Pro Sirolimus-Eluting Coronary Stent System is a drug-eluting balloon-expandable stent pre-mounted on a rapid-exchange PTCA catheter delivery system.

Indication

Synsiro Pro DES is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease due to discrete de-novo stenotic lesions and in-stent restenotic lesions (length ⩽ 40 mm) in the native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm including the following patient and lesion subsets:

Acute Coronary Syndrome (ACS)	Long Lesions (LL) (e.g. ⩾ 20 mm)
ST-Elevation Myocardial Infarction (STEMI)	Small Vessels (SV) (e.g. ⩽ 2.75 mm)
Diabetes Mellitus (DM)	Multi-Vessel Disease (MVD)
Complex Lesions (B2/C)	Male/Female
High Bleeding Risk (HBR)	Old Patients (e.g. > 65 y)

Technical Data

Stent

Stent material	Cobalt chromium, L-605
Strut thickness	ø 2.25 – 3.0 mm: 60 µm (0.0024"); ø 3.50 – 4.0 mm: 80 µm (0.0031")
Passive coating	proBIO (Amorphous Silicon Carbide)
Active coating	BIOlute bioabsorbable Poly-L-Lactide (PLLA) eluting a limus drug
Drug dose	1.4 µg/mm²

Delivery System

Catheter type	Rapid exchange
Recommended guide catheter	5F (min. I.D. 0.056")
Guide wire diameter	0.014"
Usable catheter length	140 cm
Balloon material	Semi crystalline polymer
Coating (Distal shaft)	Hydrophilic
Coating (Proximal shaft)	Hydrophobic
Marker bands	Two swaged platinum-iridium markers
Lesion entry profile	0.017"
Distal shaft diameter	2.7F: ø 2.25 – 3.0 mm; 2.9F: ø 3.5 – 4.0 mm
Proximal shaft diameter	2.0F
Nominal pressure (NP)	10 atm
Rated burst pressure (RBP)	16 atm

Storage

Use Before Date (UBD)	24 months
Temperature	Between 15°C (59°F) and 25°C (77°F), short term excursions between 10°C (50°F) and 40°C (104°F) are allowed

Ordering Information

Stent ø (mm)	Stent Length (mm) 9	13	15	18	22	26	30	35	40
2.25	419155	419161	419167	419173	419179	419185	419191	419197	419203
2.5	419156	419162	419168	419174	419180	419186	419192	419198	419204
2.75	419157	419163	419169	419175	419181	419187	419193	419199	419205
3.0	419158	419164	419170	419176	419182	419188	419194	419200	419206
3.5	419159	419165	419171	419177	419183	419189	419195	419201	419207
4.0	419160	419166	419172	419178	419184	419190	419196	419202	419208

1. In comparison to Xience Sierra, Resolute Onyx and Synergy for bench tests on pushability, trackability and crossability, BIOTRONIK data on file; 2. As characterized with respect to strut thickness in Bangalore et al. Meta-analysis; 3. Based on investigator's interpretation of BIOFLOW-V primary endpoint result.

Δ Clinical data collected with Orsiro and Orsiro Mission bench performance testing can be used to illustrate Synsiro Pro clinical safety and performance.

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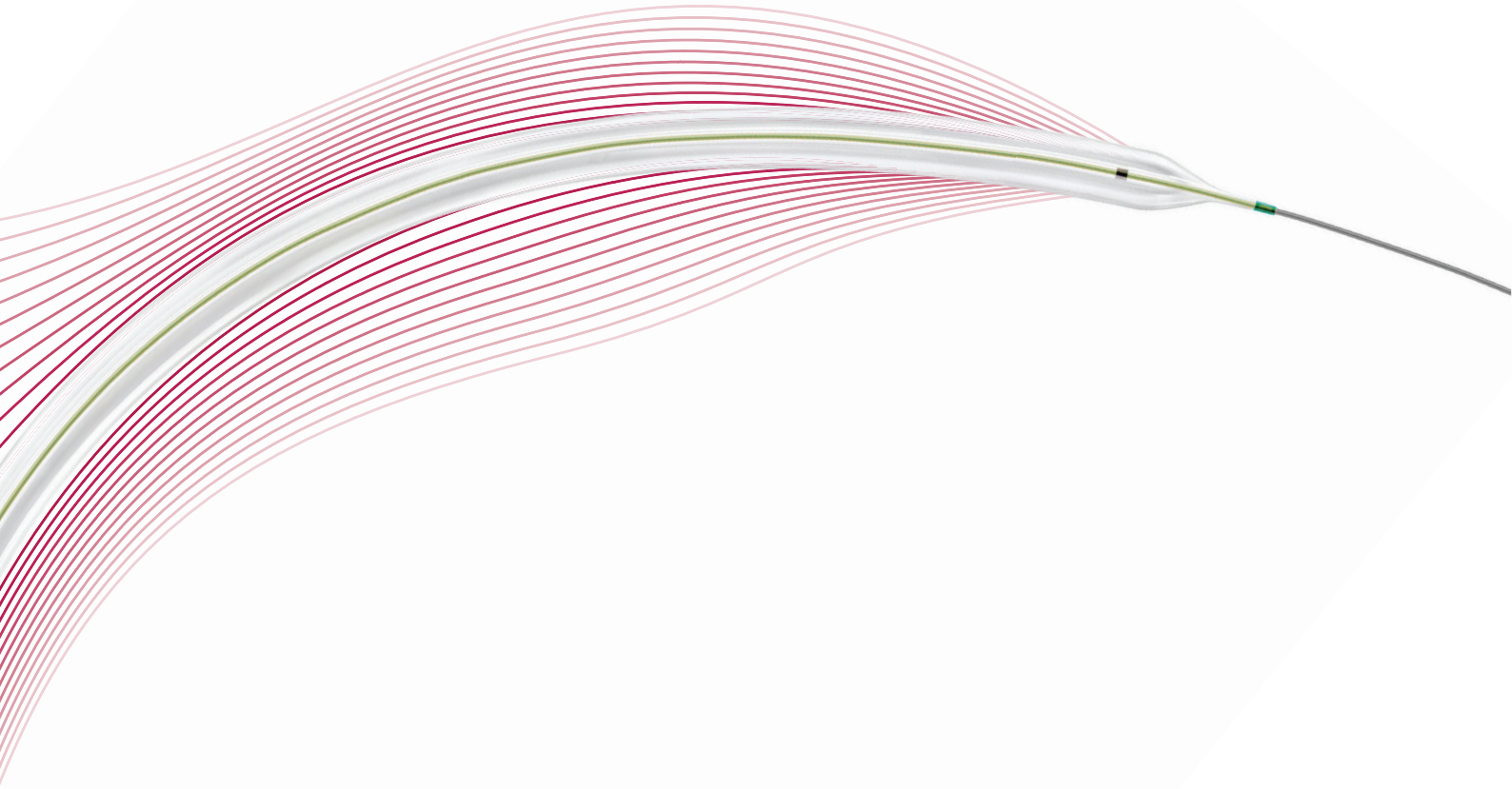
Passeo®-18

Low profile PTA balloon with high pushability in a wide range of sizes.



- High pushability
- Controlled compliance
- Low profile and wide range of sizes

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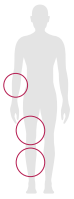
Passeo®-18

Indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.*

Vascular Intervention Peripheral



Technical Data

Balloon catheter

Catheter type	OTW
Recommended guide wire	0.018"
Tip	Short and tapered, colored
Balloon material	SCP (Semi-Crystalline Polymer), controlled compliance (4 - 8 %)
Balloon folding	5-fold
Balloon coating	Hydrophobic patchwork coating
Balloon markers	2 swaged markers (zero profile)
Sizes	ø 2.0 - 7.0 mm; L: 20 - 200 mm
Shaft	3.8F, 3.9F (ø 6.0/7.0 mm x 170 - 200 mm); coaxial design
Usable length	90, 130 and 150 cm

Compliance Chart

Balloon diameter x length (mm)

		ø 2.0 x 20-170	ø 2.0 x 200	ø 2.5 x 20-170	ø 2.5 x 200	ø 3.0 x 20-170	ø 3.0 x 200	ø 3.5 x 20-170	ø 3.5 x 200	ø 4.0 x 20-150	ø 4.0 x 170-200	ø 5.0 x 20-120	ø 5.0 x 150	ø 5.0 x 170-200	ø 6.0 x 20-200	ø 7.0 x 20-200
Nominal Pressure (NP)	atm*	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
	ø (mm)	2.0	2.0	2.5	2.5	3.0	3.0	3.5	3.5	4.0	4.0	5.0	5.0	5.0	6.0	7.0
Rated Burst Pressure (RBP)	atm*	15	14	15	14	15	14	15	14	15	13	15	12	13	12	12
	ø (mm)	2.1	2.1	2.6	2.6	3.2	3.2	3.7	3.7	4.3	4.2	5.3	5.2	5.2	6.2	7.3

*1 atm = 1.013 bar

Ordering Information

Antegrade approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	60	80	120	150	170	200
90	2.0	366098	366099	366100	366104	366105	366106	366114	376276
90	2.5	357451	357458	366101	357469	357476	366107	357483	376277
90	3.0	357452	357459	366102	357470	357477	366108	357484	376278
90	3.5	357453	357460	366103	357471	357478	366109	357485	376279
90	4.0	357454	357461	357465	357472	357479	366110	376272	376280
90	5.0	357455	357462	357466	357473	357480	366111	376273	376281
90	6.0	357456	357463	357467	357474	357481	366112	376274	376282
90	7.0	357457	357464	357468	357475	357482	366113[a]	376275[a]	376283[a]

Retrograde approach

Catheter Length (cm)	Balloon ø (mm)	Balloon Length (mm) 20	40	60	80	120	150	170	200
150	2.0	366115	366118	366119	366123	366126	366129	366137	376296
130	2.5	357486	357491	366120	357502	357507	366130	357512	376297
130	3.0	357487	357492	366121	357503	357508	366131	357513	376298
130	3.5	357488	357493	366122	357504	357509	366132	357514	376299
130	4.0	357489	357494	357498	357505	357510	366133	376292	376300
130	5.0	357490	357495	357499	357506	357511	366134	376293	376301
130	6.0	366116	357496	357500	366124	366127	366135	376294	376302
130	7.0	366117	357497	357501	366125	366128	366136[a]	376295[a]	376303[a]

[a]8 weeks pre-order only

*Indication as per IFU.

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